SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND LIN-KRIS PHARMACY, INC. d/b/a HILLSBORO PHARMACY

Come now Lin-Kris Pharmacy, Inc. d/b/a Hillsboro Pharmacy ("Respondent" or "Hillsboro Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the Complaint which was filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2002005825, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo. The parties agree that this Settlement Agreement and any statements contained herein may not be used for or constitute an admission for any purposes other than to settle the disputes between the parties.

JOINT STIPULATION OF FACTS

- 1. Petitioner, the Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by Section 338.110, RSMo, for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.
- 2. Respondent, Lin-Kris Pharmacy, Inc. d/b/a Hillsboro Pharmacy ("Hillsboro Pharmacy"), holds a pharmacy permit issued by the Board, Permit No. 2002005825, to operate a pharmacy at 283 Main Street, P.O. Box 257, Hillsboro, Missouri. Hillsboro Pharmacy's permit is, and was at all times relevant herein, current and active.
- 3. At the time of the events alleged herein, Roy H. Eberhart, II was the president of Lin-Kris Pharmacy, Inc. d/b/a Hillsboro Pharmacy.
- 4. Kellie L. Rider was employed as pharmacist-in-charge of Hillsboro Pharmacy until September 13, 2005, at which time Roy H. Eberhart, II was employed by Hillsboro

Pharmacy as pharmacist-in-charge.

4

- 5. Steven Alvey is currently employed as pharmacist-in-charge of Hillsboro Pharmacy.
- 6. On or about February 27, 2004, an inspection performed by the Board at the Hillsboro Pharmacy revealed a #500-size manufacturer container of Hydrocodone/APAP 5/500 which contained #575 tablets. This container was overfilled and mislabeled.
- 7. On or about April 15, 2004, a follow-up inspection by the Board at the Hillsboro Pharmacy revealed a #100-size manufacturer container of Paxil 20 mg. which contained #122 tablets. This container was overfilled and mislabeled.
 - 8. Section 338.059.2, RSMo, states:
 - 2. The label of any drug which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.
- 9. Title 21 U.S.C. Section 352, Misbranded drugs and devices, states in pertinent part:

A drug or device shall be deemed misbranded --

- (a) False or misleading label. If its labeling is false or misleading in any particular . . .
- 10. Respondent's conduct caused a drug to be misbranded as defined by Title 21 U.S.C., Section 352.
 - 11. Pursuant to Section 196.100.1, RSMo, a drug becomes misbranded when:

When drug or device misbranded.

1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal

labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated hereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

12. Section 196.015, RSMo, states in pertinent parts:

The following acts and the causing thereof within the state of Missouri are herby prohibited:

- (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
 - (2) The adulteration or misbranding of any food, drug, device or cosmetic;

* * *

- (9) The alteration, mutilization, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded.
- 13. Respondent violated and assisted or enable another person to violate Missouri rules and regulations governing the practice of pharmacy by causing a drug to become misbranded by overfilling and mislabeling manufacturer's containers.
- 14. Respondent should have known that violations of pharmacy laws or rules had occurred.
- 15. On or about October 28, 2005, the Board received a Change of Pharmacist-In-Charge form from Respondent.
- 16. The Change of Pharmacist-In-Charge form indicated Roy H. Eberhart, II was the new pharmacist-in-charge.

- 17. On or about November 3, 2005, the Board notified Respondent that the Change of Pharmacist-In-Charge form was incomplete and requested Respondent to provide the missing information on the form.
- 18. The Board received the completed Change of Pharmacist-In-Charge form from Respondent on or about November 15, 2005.
- 19. The effective date of the change of pharmacist-in-charge was September 13, 2005.
- 20. Respondent's failure to timely file a Change of Pharmacist-In-Charge form with the Board is in violation of 20 CSR 2220-2.010.1(L) which states as follows:
 - (L) Pharmacy operations must be conducted at all times under the supervision of a properly designated pharmacist-in-charge. When a licensed pharmacist leaves the employment of a pharmacy where s/he has been pharmacist-in-charge, s/he immediately shall notify the executive director of the board of the termination of his/her services in the pharmacy. Likewise, the holder of the permit shall notify the executive director of the board of the termination of the services and give the name of the new licensed pharmacist-in-charge.
- 21. Respondent violated and assisted or enable another person to violate Missouri rules and regulations governing the practice of pharmacy by failing to timely file with the Board a complete and accurate Change of Pharmacist-In-Charge form.
- 22. Respondent should have known that violations of pharmacy laws or rules had occurred.

JOINT CONCLUSIONS OF LAW

23. Cause exists to discipline Hillsboro Pharmacy's permit pursuant to 20 CSR 2220-2.010(1)(N), which states:

- (N) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.
- 24. Cause exists for Petitioner to take disciplinary against Hillsboro Pharmacy's permit under Section 338.285, RSMo, which states:

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

- 25. Cause exists for Petitioner to take disciplinary action against Hillsboro Pharmacy's permit under Section 338.055, RSMo, which states in relevant parts:
 - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

- 1. Respondent's permit to operate a pharmacy shall be placed on PROBATION for a period of three (3) years. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:
 - A. Respondent shall keep the Board apprised of licensed pharmacists employed by Respondent and the individuals' current home and work addresses and telephone numbers.
 - B. Respondent shall pay all required fees for permitting to the Board and shall renew its permit prior to October 31 for each permitting year.
 - C. Respondent shall comply with all provisions of Chapter 338 and 195; all applicable federal and state drug laws, rules and regulations; and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
 - D. Respondent shall not serve as an intern training facility for interns.
 - E. Roy H. Eberhart may serve as the pharmacist-in-charge of this pharmacy for a period of ninety (90) days. The ninety (90) day period shall commence from the

effective date of this Settlement Agreement. Upon expiration of the ninety (90) days, Respondent may petition the Board to allow Roy H. Eberhart to serve as the pharmacist-in-charge of this pharmacy for an additional period. Roy H. Eberhart may not continue serving as pharmacist-in-charge of this pharmacy or any other pharmacy without prior approval of the Board.

- F. If, after disciplinary sanctions have been imposed, Respondent fails to keep its Missouri pharmacy permit current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
- G. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 338, 610, and 620, RSMo.
- H. Respondent shall conduct an Initial Inventory at this pharmacy on all scheduled controlled substances, plus Carisoprodal. The Initial Inventory shall be immediately available to a member of the Board or the Board of Pharmacy staff.
- I. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.
- J. Respondent shall select an independent consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Respondent shall submit documentation and credentials of his chosen consultant to the Board office for approval prior to the beginning date of

probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense.

- K. Visits and reports of the consultant can be reduced to an annual visit after two (2) years pending performance and compliance with this Agreement and with the state and federal drug laws.
- 2. Upon the expiration of said discipline, Respondent's permit to operate a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.
- 3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.
 - 4. If the Board determines that Respondent has violated a term or condition of this

Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

- 5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- 6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement

Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

REQUESTS

DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

LIN-KRIS PHARMACY, INC. d/b/a HILLSBORO PHARMACY

By:

President

Date: 1-08-2008

By:

Debra C. Ringgenberg

PETITIONER

PHARMACY

MISSOURI BOARD OF

Executive Director

1-25-08

Date:

ARMSTRONG TEASDALE LLP

By:

Kim S. Burton #54090

3405 West Truman Blvd.

Jefferson City, MO 65109-5713

Telephone: 573/636-8394

Fax: 573/636-8457

Attorneys for Respondent

NEWMAN, COMLEY & RUTH

P.C.

Robert K. Angstead

601 Monroe, Suite 301

P.O. Box 537

Jefferson City, MO 65102-0537

Telephone: 573/634-2266

Fax: 573/636-3306

Attorneys for Petitioner